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13. ABSTRACT <i>(Maximum 200 words)</i> <p>This is the second annual progress report of a 3 year epidemiological study into the effects on health of service in the Persian Gulf War for UK servicemen and women. During the period June 1997 to June 1998, the first stage of the project was carried out, namely the mailing of 12750 questionnaires to the study participants. Extensive efforts have been made to trace the study non responders by obtaining up-to-date current addresses. This has been done by utilising the following mechanisms:</p> <ol style="list-style-type: none"> 1. Regional Health Authorities hold addresses obtained through the participant's contact with their primary physician. In some cases this route was prohibited due to concerns over the personal information confidentiality law (Data Protection Act). 2. The Electoral register, which should record an address for all eligible voters in the UK (over 18 yrs). 3. Forces discharge address. 4. Forces pension department address. 5. Royal British Legion data base. 6. Telephone tracing was also carried out when a telephone number was available. <p>Due to the poor overall response rate after the second mailing (52%) it was decided to carry out a third mailing. This is drawing to a close, at the time of writing the report the overall response rate stands at 60.1% (Gulf: 65.0%; Era: 57.7%; Bosnia 57.6%). The main problems encountered during the year have been the need to improve the response rate, and concerns over the interpretation of the Data Protection Act which has acted to restrict the availability of address information available to the research team. This is a national problem which is currently under examination at governmental level. Security considerations have also reduced the options available for tracing non responders.</p>			
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FOREWORD

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Professor Simon Wessely

June 1998

PI - Signature

Date

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Study Outline

Background

This study was set up to address the prevalence of explained and unexplained illnesses, including chronic fatigue like symptoms, in members of the United Kingdom Armed Forces who were deployed to the Persian Gulf during the Gulf War, and two comparison groups: those who had served in peace keeping forces in Bosnia, and a group who had served in neither theatre (Era controls).

Aims

This epidemiological study aims to ascertain whether service in the Persian Gulf War by UK armed forces personnel was associated with an increase in physical and / or psychological morbidity compared to those who were not deployed or those deployed to Bosnia. If it is so, evidence will be sought for an increase in known disorders, new or ill-defined conditions such as chronic fatigue syndrome, or an illness peculiar to Gulf War service.

In the event that there is, the researchers will examine the self assessed effect of deployment related exposures such as pesticides, vaccinations and psychological trauma as well as pre morbid and psychosocial factors which may be implicated in such an increase. We anticipate that this will identify avenues for further biological and psychosocial research.

Methodology

The epidemiological study of the prevalence of unexplained illnesses in the population at risk utilises a two stage design. Stage 1 will be a questionnaire survey of 4250 Gulf War veterans selected at random, an equivalent sample of Bosnia Veterans and Era controls. The second stage will involve interview, examination and testing of all those (approximately 10%) in the first stage who score above a cut off defining subjective ill health. Information gathered at the second stage will be used to estimate the prevalence of diagnosed and unexplained morbidity, including chronic fatigue, in UK personnel, and to calculate whether there is an excess associated with Gulf War and / or Bosnia service.

The studies at stage 2 will enable the team to assess more precisely the pathogenesis of the disorder uncovered in stage 1.

Progress to date

The work of the second year has been involved mainly with obtaining responses to the stage one questionnaire. This has involved carrying out 3 mailings, and the setting up and execution of extensive tracing mechanisms for non responders.

Running in parallel with this has been the planning for the second stage. Six key areas have been identified for the second phase: (Neuropsychological functioning; Neuromuscular functioning; Psychiatric assessment; Clinical examination;

Respiratory functioning; Immunological functioning), a list of the collaborators for these areas is given at the end of the report.

Stage 1: Questionnaire Response Rate.

The first mailing of the questionnaire started in July 1997 with the second mailing starting in November 1997. In the second and third mailings, the participants were requested to return the questionnaire to us incomplete if they did not wish to participate in the study. The response rates after the first two mailings are shown in table 1.

Table 1 Cumulative response rates to stage 1 questionnaire, after 1st and 2nd mailing

	Bosnia N=4228	Era N=4128	Gulf N=4214	Overall N=12570*
	n (%)	n (%)	n (%)	n (%)
1st Mailing				
Yes ¹	1506 (35.6)	1489 (36.1)	1847 (43.8)	4842 (38.5)
RTS ²	101 (2.4)	236 (5.7)	219 (5.2)	556 (4.4)
NR ³	2621 (62.0)	2403 (58.2)	2148 (51.0)	7172 (57.0)
2nd Mailing				
Yes	2058 (48.7)	2058 (49.9)	2442 (57.9)	6558 (52.0)
RTS	242 (5.7)	341 (8.3)	361 (8.6)	944 (7.5)
PR ⁴	46 (1.1)	71 (1.7)	41 (1.0)	158 (1.3)
NR	1882 (44.5)	1658 (40.2)	1370 (32.5)	4910 (39.1)

¹ returned a completed questionnaire

² questionnaire "Returned to Sender"

³ Non Responder

⁴ Participation in study refused

* This does not equal 12750 as the study team could not obtain an address , from any source, for 180 participants.

Due to the unsatisfactory overall response rate at the end of the second mailing (52%) it was decided to embark on a third mailing. For the first two mailings the questionnaire was sent to the study participants directly. A different approach for the third mailing in an attempt to boost the response rates. The sample for our study was drawn from the three services (Army, Royal Navy and the Royal Airforce); each with their own command structures. For the Army, the Commanding Officer for each unit containing study non participants was sent the relevant questionnaire(s) and asked to disseminate them to the appropriate individuals.

For the Royal Navy, the questionnaires were sent to the commanding officer for the relevant ships, with similar instructions. For the Royal Airforce, the questionnaires were sent to officer commanding the "Personnel Services Flight" at each airforce base. This is currently underway, the preliminary response rates are shown in table 2

Table 2 Cumulative response rates to stage 1 questionnaire, after 3rd mailing

	Bosnia N=4228		Era N=4128		Gulf N=4214		Overall N=12570	
	n	(%)	n	(%)	n	(%)	n	(%)
3rd Mailing								
Yes ¹	2438	(57.7)	2378	(57.6)	2728	(64.7)	7544	(60.1)
RTS ²	237	(5.6)	250	(6.1)	307	(7.3)	794	(6.3)
PR ³	97	(2.3)	173	(4.2)	90	(2.1)	360	(2.8)
NR ⁴	1456	(34.4)	1327	(32.1)	1089	(25.8)	3872	(30.1)

¹ returned a completed questionnaire² questionnaire "Returned to Sender"³ Participation in study refused⁴ Non Responder

Tracing non responders

After the first mailing, several means were employed to help trace study non responders. These tracing mechanisms have been followed in parallel, which has resulted occasionally in the team obtaining several addresses for a particular study participant.

The main routes used have been:

1. Telephone contact with non responders
2. Health authorities
3. Electoral Register
4. Discharge addresses / Pension addresses

1. Telephone contact

A research assistant was employed from January 1998 in order to ring ex service non responders, to try and encourage them to participate in the study. In order to ring them, telephone numbers were obtained from Directory Enquiries and a British Telecom CD. It was quickly discovered that half of the non responding participants were not listed as having a telephone at any of the addresses we held for them, as shown in table 3.

This could be considered a proxy measure of the accuracy of the address information for our study non responders; however it is impossible to say whether no listing means that the participant was at the address or not, it only means that a phone was not registered in the non responders name at that address.

Table 3 Frequency of ex directory (EX-D) no listing (NL) and obtained number for ex service non responders, by cohort.

	Bosnia		Era		Gulf		Total	
	n	(%)	n	(%)	n	(%)	n	(%)
EXD	75	(18.6)	283	(21.8)	266	(22.8)	624	(21.7)
NL	216	(53.6)	656	(50.5)	567	(48.6)	1439	(50.2)
Obtained number	112	(28.0)	361	(28.0)	333	(29.0)	806	(28.0)

Of those individuals contacted by phone who agreed to participate in our study, 70% returned their questionnaire to us (63% completed it, 7 % returned it blank, i.e. were refusing to participate in the study).

2. Electoral Register

In order to try to estimate how many of the ex service non responders were actually registered as living at the address we held for them , staff were despatched to the central electoral register on the south coast of England. This was a very time consuming process as it involved manually searching boxes of paper records for individuals. Due to the resource limitation of the project, a sample (489)of the addresses held for the non respondents were examined. Of the 489 investigated, only 161 (32.9%) were registered at that address as of 1997. This suggests that the figure obtained from the Directory Enquiries/BT CD (28%) is a slight underestimate of the accuracy of the addresses held for non responders.

3. Health Authorities

During the Autumn 1997, it became apparent that a serious problem existed regarding the tracing of ex service non responders for the UK Gulf War Studies. Contact had been made with Chief Executives of the 106 Health Authorities (Regional administrative offices for the National health Service) in the UK, asking for their permission to provide us with addresses they hold for our study non responders. As a result of this , the Data Protection Registrar (the officer who oversees the ???? of the data Protection Act) deemed it a breach of confidentiality for the Health Authorities to provide us with this information, as it was in breach of the Data Protection Act. This has introduced a lengthy delay in the release of information for the studies, an issue which is still under discussion.

In light of this problem, the Ministry of Defence chaired several meetings with the UK Gulf War Studies groups, with the aim of aiding the studies in tracing non responders by alternative routes. Alternative sources investigated were:

- Inland Revenue (IR)
- Department of Social Security (DSS)
- Department of Vehicle Licensing Association (DVLA)

Both the IR and DSS were unwilling to help due to the Data Protection Act. However, the DVLA was willing to undertake a limited mailshot on behalf of the study. This was used as part of the extensive tracing methods used for 200 non responders (see **Non Response Bias** section below)

4. Discharge Addresses / Pension addresses

The MoD supplied the team with addresses supplied on discharge from the forces, and addresses supplied for pension registration.

In addition to the 4 mechanism out line above, the following address sources were investigated.

5. Royal British Legion (RBL) data base

As mentioned in the first annual report, the Royal British Legion were willing to allow us access to their membership data base to see if we could find more up to date address information for our study subject. A randomly select sample of 100 individuals was checked against this database, only 6 individuals were registered with the RBL. Thus it was determined that this database was not a rich source for tracing study non responders.

6. Medical Assessment Program (MAP)

The British Government made a medical assessment available to all those UK Gulf War Veterans who requested it. It was determined that a certain percentage of our Gulf cohort had attended this program, and so the MAP would have a reliable address for these individuals. In lines with the DPA, the MAP did not disclose these addresses to the team, but instead forwarded the questionnaires to the MAP participants.

Non Response Bias

The issue of non response bias is of great importance to this study. 100 ex serving non responders were randomly selected (50 from the gulf Cohort , 25 from the Era and Bosnia Cohorts respectively), this was replicated for those still in service. Every effort is being made to trace this group of 200 non responders in order to investigate any potential bias that may be present in this group, including asking the DVLA to forward the questionnaires to this group on our behalf.

Publicity

Steering group Committee

The Steering Group Committee met three times during the year. The committee felt that with all the obstructions taken into account, the study was in fact progressing very well.

Media articles

Building on the publicity of the first year, articles were published in the national press, as well as in the forces magazine. One article published in a national tabloid newspaper requested that individuals who saw service in the Gulf conflict ring and register their current address with the UK Gulf War Study Team, in order enable us to send them questionnaires. This yielded 70 addresses for the King's Study.

Gulf Veteran Associations

Regular contact was been made with the various Gulf War Veteran associations, to keep them informed of the progress of the study. Their advice has been sought as to how best we could improve our response rate, and also to ask them to support attendance at the second phase of the study. At the start of the summer the various associations were united under a branch of the Royal British Legion.

Problems encountered.

The main problems encountered this year has been the poor response rate to the mailed questionnaire, and the role of the Data Protection Act in our obtaining accurate addresses for the study non responders. Security considerations have limited the sources available to the study for tracing purposes.

1. Poor response rate

The poor response rate after the first two mailing necessitated the initiation of a third mailing, with the consequential delay in the starting of the second stage of the study.

2. Data Protection Act

As alluded to in the tracing section above, the most serious problem encountered this year has been the Data Protection Act, with its potential consequences not only for this research project, but for medical research in the future. The Ministry of Defence has given their total support in this matter, and a meeting is planned between a representative of the UK Gulf War Studies ,the Minister for the Armed forces and the Data Protection Registrar to see if there is any possible way around this matter.

3. Security considerations

The use of commercial enterprises for tracing the study non responders was investigated. Their use was strictly forbidden as it was felt they could represent a security risk, thereby removing a powerful tracing tool.

Additional funding

During the year additional funding for the study has been obtained form three sources:

- 1 Neurophysiological studies of Gulf related illnesses
(Rose, Wessely, David) MOD, £212,000. 1998 - 2000
- 2 Autoantibodies to nuclear envelope antigen in Chronic Fatigue Syndrome and
Gulf related illness
(Peakman, Wessely) Linbury. £36,265, 1998-1999
- 3 Specimen collection and storage, Gulf related illness
(Wessely, Peakman) MRC £47,551 1998-1999

Staff Recruitment

Two more staff have been appointed for the second stage of the study; a research nurse and a neuropsychologist. Both were selected from a very strong field of candidates, in response to nationally placed adverts.

Future planning

Once the first phase of the project is completed, individuals identified as "cases", along with appropriate comparison group, will be invited to attend for the second phase of the study. The six areas to be investigated are:

- Neuropsychological functioning
- Neuromuscular functioning

- Psychiatric assessment
- Clinical examination
- Respiratory functioning
- Immunological functioning

Study Personnel

Study Co directors

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Professor Anthony David MD.

Study Co-ordinator

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BSc, MSc Epidemiology

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BSc Applied Psychology and Sociology

Secretary

Ms Jo Williams

Military Advisors

i) Up to March 1997: Lieutenant Colonel John Graham

From April 1997: Lieutenant Colonel Phil Bolton

ii) Lt Col. Ian Palmer

Statistician

Dr. Nick Blatchley

Phase 2 Collaborators

- Medical examination Dr Khalida Ismail
- Psychiatric Interview

- Neuropsychology Dr Til Wykes

-

- Neuromuscular symptoms study Dr Michael Rose
Dr Mohammed Sharief
